to charge any additionally required fee for the extension, or any other fee occasioned by this paper, or credit any overpayment in such fees, to Deposit Account No. 50-0320.

## REMARKS

Reconsideration and withdrawal of the requirement for election of species is respectfully requested in view of the remarks herewith, which place the application in condition for allowance.

The June 19, 2002 Office Action required an election under 35 U.S.C. § 121 from:

- **Group I.** Claims 1-19, drawn to a method for obtaining an immunogenic response using a nucleic acid, classified in class 514, subclass 44; and
- **Group II**. Claims 20, drawn to a kit comprising a nucleic acid, classified in class 536, subclass 23.1.

The June 19, 2002 Office Action identifies generic claims 1-19, and requires an election of species from BHV-1, BRSV, BVDV, bPI-3, PRV, PRRSV, and SIV.

The invention of Group I, claims 1-19 drawn to a method for obtaining an immunogenic response using a nucleic acid, is elected, for further prosecution in this application. This election is made *with traverse* and is made without prejudice to Applicants' right to file divisional applications directed to the non-elected subject matter. It is respectfully requested that the restriction requirement be favorably reconsidered and withdrawn.

The species BRSV, recited in claims 1, 4, 5 and 16-20, is also elected. This election is also made *with traverse* as the species are each related to one another and directed to the same inventive concept and are capable of being simultaneously searched.

It is understood that the Examiner can broaden the search to include other species, e.g., upon determining that a species is allowable, or as discussed herein, when there is a relationship among the species and/or number of species is not too great. It is understood that upon the allowance of a generic claim, Applicants will be entitled to consideration of claims to additional species which are written in dependent form or which otherwise include all of the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141.

Favorable reconsideration and withdrawal of the requirement for restriction from among Groups I and II is respectfully requested. Applicants respectfully traverse the restriction and election requirements. The inventive concept linking Groups I and II of the claimed invention

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lies in the enhancement of the efficacy of DNA vaccination or immunization against bovine and porcine pathogens. The present invention relates to, *inter alia*, improved methods for obtaining an immunogenic response using a nucleic acid composition. The aforementioned nucleic acid composition is included in a kit claimed in Group II. It is respectfully pointed out that the Examiner, in defining the subject matter of Group II, failed to recognize that the kit of claim 20 is dependent on claim 1, *i.e.*, claim 20 depends upon claim 1 and comprises the limitations of claim 1.

It is respectfully submitted that the claims in Groups I and II may be searched and examined together without serious burden, as they relate to improved methods for obtaining an immunogenic response. For example, the claim of Group II is directed to a kit containing the elements of Group I, and is dependent on claim 1. Thus, a search of the claims of Group I would necessarily include a search of the claim of Group II.

The Examiner's requirement for restriction for Groups I and II was made pursuant to the provisions of the M.P.E.P. §806.05(h). It is alleged by the Examiner that the inventions are patentably distinct from each other because, "In the instant case the product (nucleic acid compositions) can be used in a materially different process such as: a template for a PCR reaction, a probe in a hybridization assay, expressing encoded protein in vitro, and in the production of antibodies specific to the nucleic acid." (Office Action at 2).

It is respectfully submitted that the criteria necessary for classifying Groups I and II as distinct inventions has not necessarily been met.

Thus, contrary to the above views expressed by the Examiner, it is highly unlikely that the method claims of Group I can be practiced with another materially different product or the product claims (i.e. kit) of Group II can be used in a materially different process. Claim 20 is dependent on claim 1, and as such, contain all the limitations of claim 1; thus, the Group II product claims cannot be made by a "materially different process."

Even if the nucleic acid compositions of Group I can be used in a materially different process, as suggested in the Office Action (Office Action, at 2), the nucleic acid compositions of Group II are directly related to the claims of Group I and a search of the claims of Group I would necessarily include a search of the claim in Group II. Thus, it is respectfully asserted that the

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claims of Groups I and II should be joined together, since the Group I search would encompass a search and examination of the Group II kits.

Further, it is respectfully asserted that the claims of Groups I and II are related to the same inventive concept. The kit claimed in Group II is specially adapted to carry out the methods claimed in Group I. One of skill in the art would appreciate that the improved methods for obtaining an immunogenic response using a nucleic acid composition of Group I may be used to practice the claim of Group II.

Therefore, it is maintained that a search of the invention of Group I would substantially overlap with the searches for the claim of Groups II and would not present an undue burden.

It is noted that the Examiner has presented no evidence that a separate search for Group I would be required for action on the merits as to Group II. It is believed that a proper search to determine the patentability of the methods of claims 1-19 of Group I would include the kit, as defined in claim 20. Applicant kindly refers the Examiner to a provision of the MPEP §803, which provides that, even if restriction is proper:

If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to distinct or independent inventions.

In the present case, it is courteously submitted that a search and examination of the claims in Groups I and II can be made without serious burden.

Simply, searching and examining the claims of Group I would consequently and inextricably encompass searching and examining the claims included in Group II.

Moreover, it is respectfully submitted that the Examiner has not made the requisite showing of serious burden as to Groups I and II, such that restriction of the claims among Groups I and II, it is respectfully submitted, is improper.

The Examiner will have to study Applicant's entire application in connection with his examination of the elected invention. No additional effort will be required to study the application with respect to the claim 20.

It is respectfully submitted that Groups I and II designated by the Examiner do not warrant separate examination and search. Accordingly, the restriction requirement should be

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reconsidered and withdrawn, especially given that the requisite showing of serious burden has not been made. Therefore, it is respectfully submitted that, Groups I and II be rejoined.

With regard to the election of species requirement, it is respectfully requested that the requirement for species election be reconsidered and withdrawn and, in this regard, the Examiner is respectfully requested to review M.P.E.P. § 808.01(a) which states that "where there is no disclosure of relationship between species (*see* M.P.E.P. §806.04 (b)), they are independent inventions and election of one invention" is required (July 1998). In view of M.P.E.P. § 803, however, when the generic claim includes sufficiently few species that a search and examination of all the species at one time would not impose a serious burden on the examiner, then a requirement for election is inappropriate. The species of BRSV, BHV-1, BVDV, bPI-3, PRV, PRRSV and SIV are not too great in number; they can be searched without serious burden. At the very least, the group of bovine pathogens could be searched and examined together. Therefore, the request for species election should be reconsidered and withdrawn, or regrouped, e.g., so that all bovine pathogens are searched and examined together in this application.

It is also respectfully urged that restricting the claims in the manner suggested in the election of species requirement constitutes an undue burden to the Applicants. If followed, the election of species requirement would require Applicants to file a number of additional applications. The cost of prosecuting and maintaining additional patents is unreasonable in view of the fact that the application as filed includes claims that are all related to one another. Further, under GATT, the period of exclusivity for any patents that issue from these divisional applications is greatly reduced. In addition, the public is inconvenienced, as it will not know whether or not Applicants will file divisional applications to the remaining subject matter. Accordingly, the public will not know if they can practice the remaining invention without infringing future patent applications.

## **CONCLUSION**

Accordingly, in view of the foregoing, reconsideration and withdrawal of the requirements for restriction and for election of species or at least a regrouping, e.g., with all bovine pathogens being searched and examined together in this application is respectfully requested, and an early action on the merits is also earnestly solicited.

Respectfully submitted,

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